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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,244	07/23/2003	Nicholas V. Perricone	00961-P0213A	3183

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EXAMINER
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OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/625,244

**Applicant(s)**

PERRICONE, NICHOLAS V.

**Examiner**

Simon J. Oh

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 12 January 2005.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12, 14-18, 21, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

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(1) The nature of the invention:

The invention provides for topical compositions comprising an effective amount of an allithiamine, such as benfotiamine. Methods for treatment and prevention of aging and/or other skin conditions are also recited.

(2) The state of the prior art

The art has taught that allithiamines, such as benfotiamine, are useful as a component in topical compositions. However, the art is silent with respect to the use of this component in the actual prevention of aging or glycation.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

With respect to those claims that recite the prevention of aging, in the view of the examiner, the art has set forth that aging cannot be completely prevented in any predictable manner.

(5) The breadth of the claims

The claims are very broad. The instantly claimed methods recite that the prevention of aging and/or glycation is entirely attributable to the administration of an allithiamine, such as benfotiamine.

(6) The amount of direction or guidance presented

The specification does not present any data that conclusively shows that aging and/or glycation can be entirely prevented due to the administration of a composition comprising an

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allithiamine, such as benfotiamine. The instant disclosure states in Paragraph 0004 that benfotiamine is believed to prevent sugars in cells from combining with proteins to form advanced glycation endproducts. This statement seems to suggest that the specific pharmacokinetic behavior of benfotiamine is not entirely understood.

(7) The presence or absence of working examples

No working examples have been provided which show that the instantly claimed invention prevents aging or glycation.

(8) The quantity of experimentation necessary

In the view of the examiner, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine conclusively that the complete prevention of aging and/or glycation can be achieved in a manner that is directly attributable to the administration of an allithiamine, such as benfotiamine.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Runge *et al.* and Woerwag *et al.* is maintained.

***Response to Arguments***

Applicant's arguments filed 12 January 2005 have been fully considered but they are not persuasive.

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In response to applicant's argument that the references fail to show the prevention and treatment of glycation and aging due to glycation, it is the position of the examiner that there is insufficient disclosure that significantly differentiates between the conditions disclosed by the prior art and that which is recited in the instant claims. It is noted that the symptoms recited by the applicant due to glycated proteins, such as inflammation, irritation, and uneven coloring are also symptoms shared by conditions disclosed in the prior art, such as rheumatic disorders and shingles. The prior art has already broadly disclosed that topical benfotiamine compositions are useful for the treatment of skin conditions. Thus, the applicant has failed to show how the instant claims are patentably distinct above the prior art.

Additionally, with regard to Claims 1-9, 19 and 20, the amendments made to independent claims 1 and 19 do not render them patentably distinct above the prior art. The portion of the preambles that have been amended amount to a recitation of intended use. As these claims are directed towards compositions, such a recitation is not given significant patentable weight. All pending claims remain rejected.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

sj0

THURMAN K. PAGE  
SUPERVISOR OF PATENT EXAMINER  
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